510(k) SUMMARY – Biomerix Vascular Occlusion Device

Applicant Name:	Biomerix Corporation 41 West 57th Street, 6th Floor New York, NY 10019 Phone: (212) 980-1951 Fax: (212) 752-3633
Contact Person:	Craig Friedman, M.D. VP, Medical Research and Development
Date Prepared:	December 7, 2004
Device Trade Name:	Biomerix Vascular Occlusion Device and Loader
Device Common Name:	Arterial embolization device
Classification Name:	Device, embolization, arterial
Predicate Devices:	Cook Embolization Coils, K942189 Amplatzer® Vascular Plug, K031810
Device Description:	The Biomerix Vascular Occlusion Device is a cylindrical device made from polycarbonate-urethane. The length of the implant is 15 mm, and it is available in diameters of 4, 6, and 8 mm. The Biomerix Vascular Occlusion Device is provided sterile for single use in its uncompressed state. The device is compressed and delivered to the target location through a commercially available peripheral introducer (5-7 F). A Loader is provided to assist with introducing the implant into the delivery catheter.
Intended Use:	The Biomerix Vascular Occlusion Device is intended for arterial and venous embolization in the peripheral vasculature.
Device Technological Characteristics and Comparison to Predicate Device(s):	The Biomerix Vascular Occlusion Device is similar in performance to Cook Stainless Steel coils. Both devices disrupt blood flow, causing thrombus formation and occlusion. Coils are composed of stainless steel and synthetic fibers. The Biomerix Vascular Occlusion Device is similar in design to the Amplatzer® Vascular Plug. The Amplatzer® is also a cylindrical plug, which is available in diameter ranging from 4 to 16 mm. The Amplatzer® is composed of Nitinol, platinum, and stainless steel.

Performance Data:	Material testing was performed to demonstrate that the material properties are suitable for the intended use. Bench testing was performed to demonstrate that the devices as manufactured meet the performance specifications for loading, deliverability, and recovery. Extensive biocompatibility testing was performed to demonstrate that the material is safe and biostable. Animal testing demonstrates that the device performs equivalently to Cook Embolization Coils in terms of time to occlusion, migration, recanalization, and tissue response.
Conclusion:	Based on the material, bench, and animal testing, and the proposed device labeling, the Biomerix Vascular Occlusion Device and Loader is substantially equivalent to the identified predicate devices in terms of intended use, safety, and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 3 2005

Ms. Christina Kichula, RAC
Manager, Regulatory Affairs
Biomerix Corporation
c/o PPD Medical Device
1700 Rockville Pike, Suite 400
Rockville, MD 20852

Re: K043371
Trade/Device Name: Biomerix Vascular Occlusion Device
Regulation Number: 21 CFR 870.3300
Regulation Name: Arterial Embolization Device
Regulatory Class: Class II (two)
Product Code: KRD
Dated: December 7, 2004
Received: December 8, 2004

Dear Ms. Kichula:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Lechner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043371

Device Name: Biomerix Vascular Occlusion Device

Indications For Use:

The Biomerix Vascular Occlusion Device is intended for arterial and venous embolization in the peripheral vasculature.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Kochman

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K043371